UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,507	04/22/2004	Kishore Udipi	P1422 US (2650/98)	7359

28390 7590 03/02/2009

MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER	
OU, JING RUI	
ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
03/02/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/829,507	UDIPI ET AL.	
	Examiner	Art Unit	
	JING OU	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2008 and 15 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-20,29-31,33-37 and 41-53* is/are pending in the application.

4a) Of the above claim(s) *41-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-20,29-31,and 33-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to the amendment filed on 10/09/2008 and election/restriction response filed on 12/15/2008. Claims 1-7, 9-20, 29-31, 33-37, and 41-53 are pending. Claims 1, 21, 29, and 41 are independent. Claims 41-53 are newly added and withdrawn from consideration. Claims 8, 21-28, 32, and 38-40 are cancelled.

Election/Restrictions

2. Applicant's election without traverse of Group I (Claims 1-7, 9-20, 29-31, and 33-37) in the reply filed on 12/15/2008 is acknowledged.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 29, 31, and 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz (US Pub. No.: 2003/0235602).

In regard to Claim 29, a drug-polymer coated stent, comprising: a stent framework (Para.[0007]); and a polymeric coating (barrier layer, Paras.[0006], [0024], [0026], and [0027]) disposed on the stent framework, wherein the polymeric coating comprises a blended matrix of a polysulfone and a styrenic block copolymer

(Para.[0005], [0045], and [0052]); and a therapeutic agent contacting the polymeric coating (Paras. [0005], [0006], and [0026]), wherein the blended matrix comprises a first fraction of the polysulfone and a second fraction of the styrenic block copolymer based on a predetermined elution rate of the therapeutic agent (Para.[0012], [0024], [0045]), wherein the ratio of first fraction of polysulfone to second fraction of styrenic block copolymer is selected so the coating has a predetermined hydrophobicity (Para.[0012], when the ratio of the first fraction of polysulfone to second fraction of styrenic block copolymer is selected, the hydrophobicity is predetermined).

In regard to Claim 31, it is inherent that the blended matrix comprises a chain length of polysulfone and chain length of styrenic block copolymer since polysulfone and styrenic block copolymer are polymer and copolymer, respectively.

In regard to Claim 33, the therapeutic agent is selected from the group consisting of an antirestenotic agent, an antisense agent, an antineoplastic agent, an antiproliferative agent, an antithrombogenic agent, an anticoagulant, an antiplatelet agent, an antibiotic, an anti-inflammatory agent, a steroid, a gene therapy agent, a therapeutic substance, an organic drug, a pharmaceutical compound, a recombinant DNA product, a recombinant RNA product, a collagen, a collagenic derivative, a protein, a protein analog, a saccharide, and a saccharide derivative (Para. [0034]).

In regard to Claim 34, the therapeutic agent is dispersed within the blended matrix of the polysulfone and the styrenic block copolymer (Para.[0033]-[0037]).

In regard to Claim 35, the therapeutic agent is positioned between the polymeric coating and the stent framework (Paras. [0005], [0006], and [0026]).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (US Pub No.: 2003/0235602).

In regard to Claim 30, Schwartz discloses all the limitations of the claims as taught above but fails to disclose that the stent framework comprises one of a metallic base or a polymeric base. Furthermore, Schwartz does not appear to disclose that the metallic base is selected from nitinol.

However, it is old and well known in the art that stent framework comprises one of nitinol or polymeric base. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a stent framework comprising of one of nitinol base or polymeric base, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability from the intended use as a matter of obvious design choice. *In re Leshin, 125 USPQ 416.*

Therefore, at the time of the invention, it would have been obvious one of ordinary skill in the art to include a catheter having a sheath and a stent framework comprising of one of nitinol base or a polymeric base to obtain the invention as specified in the instant claims.

9. Claims 1-6, 12, and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (US Pub No.: 2003/0235602) in view of Roorda et al (US Pat. No.: 7,175,873).

In regard to Claim 1, Schwartz discloses a system for treating a vascular condition, comprising: a catheter; a stent coupled to the catheter (a stent must be coupled to the catheter), the stent including a stent framework (Para.[0007]); a polymeric coating disposed on the stent framework, wherein the polymeric coating (barrier layer, Paras.[0006], [0024], [0026], and [0027]) comprises a blended matrix of a

polysulfone and a styrenic block copolymer (Para.[0005], [0045], and [0052]); wherein the blended matrix includes a first fraction comprising the polysulfone and a second fraction comprising the styrenic block copolymer (Para. [0012]), wherein the first fraction is greater than the second fraction (Fig. 2A, 50%SMA14 / 25% SIBS and Paras. [0012], [0013], and [0104]) and wherein the styrenic block copolymer (copolymer of styrene and maleic anhydride) has a molecular weight of approximately 50,000 (Para.[0021]), and a therapeutic agent in contact with the blended matrix (Paras. [0005], [0006], and [0026]).

Schwartz does not appear to disclose that the polymeric coating to be hydrophobic.

However Roorda et al discloses a hydrophobic polymeric coating on a stent (see Abstract)

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Schwartz and Roorda et al to modify the polymer coating of Schwartz to be hydrophobic as taught by Roorda et al.

The suggestion/motivation for doing so would have been to provide a steady rate of release of drug (Col. 1, lines 42-53 and Fig. 3).

Therefore, it would have been obvious to combine Roorda et al with Schwartz to obtain the invention as specified in the instant claim.

In regard to Claim 2, the catheter includes a balloon used to expand the stent (Para.[0007]).

In regard to Claim 3, Schwartz discloses all the limitations of the claim as taught above but fails to disclose that the catheter includes a sheath.

However, catheter comprising a sheath is old and well known in that art. The suggestion/motivation for including a sheath is to prevent the stent from premature deployment.

In regard to Claims 4, 5, and 30, Schwartz discloses all the limitations of the claims as taught above but fails to disclose that the stent framework comprises one of a metallic base or a polymeric base. Furthermore, Schwartz does not appear to disclose that the metallic base is selected from nitinol.

However, it is old and well known in the art that stent framework comprises one of nitinol or polymeric base. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a stent framework comprising of one of nitinol base or polymeric base, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability from the intended use as a matter of obvious design choice. *In re Leshin, 125 USPQ 416.*

Therefore, at the time of the invention, it would have been obvious one of ordinary skill in the art to include a catheter having a sheath and a stent framework comprising of one of nitinol base or a polymeric base to obtain the invention as specified in the instant claims.

In regard to Claim 6, the therapeutic agent is dispersed within the blended matrix of the polysulfone and the styrenic block copolymer (Paras.[0026], [0045], [0052], and [0062]).

In regard to Claim 12, the therapeutic agent is positioned between the polymeric coating and the stent framework (Paras. [0005], [0006], and [0027]).

In regard to Claim 14, the blended matrix of the polysulfone and the styrenic block copolymer provides a controlled elution rate for the therapeutic agent (Para.[0055]).

In regard to Claim 15, the therapeutic agent is selected from the group consisting of an antirestenotic drug, an antisense agent, an antineoplastic agent, an antiproliferative agent, an antithrombogenic agent, an anticoagulant, an antiplatelet agent, an antibiotic, an anti-inflammatory agent, a steroid, a gene therapy agent, a therapeutic substance, an organic drug, a pharmaceutical compound, a recombinant DNA product, a recombinant RNA product, a collagen, a collagenic derivative, a protein, a protein analog, a saccharide, a saccharide derivative, a bioactive agent, a pharmaceutical drug, and a combination thereof (Para.[0033]-[0037]).

In regard to Claim 16, the polymeric coating comprises a plurality of therapeutic agents (Para.[0001]), each therapeutic agent having a predetermined elution rate (Paras.[0012] and [0016])

In regard to Claim 16, the recitation, "the blended matrix of the polysulfone and the styrenic block copolymer eluting the therapeutic agents at the predetermined elution rates" is an intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (US Pub No.: 2003/0235602) as applied to claim 1 above, and further in view of Chang et al (US Pat. No.: 4,157,960).

Schwartz discloses all the limitations of the claim but fails to disclose that the polysulfone has a molecular weight between 10,000 Daltons and 100,000 Daltons.

However, Chang et al explicitly discloses that the molecular weight of the polysulfone is generally at least about 10,000 and less than about 500,000, and is frequently less than about 100,000 (Col. 8, lines 4-7).

Schwartz and Chang et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Schwartz and Chang et al before him or her, to modify the system of Schwartz to include polysulfone which has a molecular weight between 10,000 Daltons and 100,000 Daltons.

The suggestion/motivation for doing so would have been that a molecular weight less than 500,000 Daltons is suitable for film or fiber formation (Col. 8, lines 1-7).

Applicant should note that the range of molecular weight for polysulfone applied to stent is only a design choice and within the level of one of ordinary skill in the art.

Therefore, it would have been obvious to combine Chang et al with Schwartz to obtain the invention as specified in the instant claim.

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (US Pub No.: 2003/0235602) in view of Roorda et al (US Pat. No.: 7,175,873) as applied to claim 1 above, and further in view of Pacetti (WO 03/022323).

Schwartz in view of Roorda et al discloses all the limitations of the claim but fails to disclose that the polymeric coating comprises between 0.0 percent and 50 percent of the therapeutic agent by weight.

However, Pacetti explicitly teaches that a polymeric coating comprises between about 0.1% to about 40% of the therapeutical agent by weight (Para.[0026]).

Schwartz, Roorda et al, and Pacetti are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Schwartz in view of Roorda et al to include a polymeric coating comprising between about 0.1 % to about 40% of the therapeutic agent by weight as taught by Pacetti.

Applicant should note the range of percentage of the therapeutical agent by weight in polymeric coating is only a design choice and within the level of one of ordinary skill in the art.

Therefore, it would have been obvious to combine Pacetti with Schwartz and Roorda et al to obtain the invention as specified in the claim.

12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (US Pub No.: 2003/0235602) in view of Roorda et al (US Pat. No.: 7,175,873)

as applied to claim 1 above, and further in view of Cafferata (US Pub. No.: 2003/0083739).

Schwartz in view of Roorda et al discloses all the limitations of the claim but fails to disclose that the polymeric coating has a thickness between 0.5 microns and 20 microns.

However, Cafferata specifically teaches a polymeric coating that has a thickness between approximately 1 micron and about 20 microns (Para.[0035]).

Schwartz, Roorda et al, and Cafferata are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Schwartz in view of Roorda et al to include a polymeric coating that has a thickness between approximately 1 micron and about 20 microns as taught by Cafferata.

Applicant should note the range of thickness of the polymeric coating is only a design choice and within the level of one of ordinary skill in the art.

Therefore, it would have been obvious to combine Cafferata with Schwartz and Roorda et al to obtain the invention as specified in the claim.

13. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (US Pub No.: 2003/0235602) in view of Roorda et al (US Pat. No.: 7,175,873) as applied to claim 1 above, and further in view of Hossainy et al (US Pat. No.: 6,153,252).

Schwartz in view of Roorda et al discloses all the limitations of the claim but fails to disclose that the polymeric coating has a weight between 50 micrograms and 1500 micrograms.

However, Hossainy et al discloses a stent comprising a polymeric coating which has a weight between about 100-150 micrograms (Col. 11, lines 2-8).

Schwartz, Roorda et al, and Hossainy et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Schwartz in view of Roorda et al to include a polymeric coating that has a weight between approximately 100-150 micrograms as taught by Hossainy et al.

Applicant should note the range of weight of the polymeric coating is only a design choice and within the level of one of ordinary skill in the art.

Therefore, it would have been obvious to combine Hossainy et al with Schwartz to obtain the invention as specified in the claim.

14. Claims 13 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (US Pub No.: 2003/0235602) in view of Roorda et al (US Pat. No.: 7,175,873) as applied to claim 1 above, and further in view of Sirhan et al (US Pub. No.: 2003/0083646).

In regard to Claim 13, Schwartz in view of Roorda et al discloses all the limitations of the claim but fails to disclose that the therapeutic agent has a thickness between 0.1 microns and 20 microns.

However, Sirhan et al discloses a stent (expandable structure, 16, Fig. 2A) comprising a therapeutic agent that has a thickness between 0.1 microns and 5 microns (Para.[0025]).

Schwartz, Roorda et al, and Sirhan et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Schwartz to include a therapeutic agent that has a thickness between 0.1 microns and 5 microns as taught by Sirhan et al.

Applicant should note the range of thickness of the therapeutic agent is only a design choice and within the level of one of ordinary skill in the art.

Therefore, it would have been obvious to combine Sirhan et al with Schwartz and Roorda et al to obtain the invention as specified in the claim.

In regard to Claims 16-18, Schwartz in view of Roorda et al discloses all the limitations of the claims but fails to explicitly disclose that the polymeric coating comprises a plurality of therapeutic agents, each therapeutic agent having a predetermined elution rate. Schwartz in view of Roorda et al does not appear to disclose that the first therapeutic agent is concentrated adjacent to the stent framework, and a second therapeutic agent is concentrated adjacent to the outer surface of the polymeric coating. Furthermore, Schwartz in view of Roorda et al does not appear to disclose that the first therapeutic agent comprises an antirestenotic drug and the second therapeutic agent comprises an anti-inflammatory drug.

However, Sirhan et al explicitly teaches a stent (16, Fig. 2K) comprising a polymeric coating which comprises a plurality of therapeutic agents (50 and 28, Fig. 2K), each therapeutic agent having a predetermined elution rate (the rates are controlled by the rate controlling element 43 and 55, Para.[0106]). Sirhan et al also explicitly teaches that the first therapeutic agent (28, Fig. 2K) is concentrated adjacent to the stent framework, and a second therapeutic agent (50, Fig. 2K) is concentrated adjacent to the outer surface of the polymeric coating. Furthermore, Sirhan et al explicitly teaches that the first therapeutic agent comprises an antirestenotic drug (rapamycin, Paras.[0087]) and the second therapeutic agent comprises an anti-inflammatory drug (Para.[0107]).

Schwartz, Roorda et al, and Sirhan et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Schwartz in view of Roorda et al to include a plurality of therapeutic agents, a predetermined elution rate for each therapeutic agent, the first therapeutic agent is concentrated adjacent to the stent framework, and a second therapeutic agent is concentrated adjacent to the outer surface of the polymeric coating, and the first therapeutic agent comprises rapamycin and the second therapeutic agent comprises an anti-inflammatory drug as taught by Sirhan et al.

It is old and well known in the art that a stent comprises a polymeric coating which comprises a plurality of therapeutic agent and each therapeutic agent having a predetermined elution rate. The suggestion/motivation for doing so would have been to

deliver more than one therapeutic agent to the body at different rate to maximum the therapeutic effect in the body and therapeutic need by the body.

Applicant should note the first therapeutic agent is concentrated adjacent to the stent framework, and a second therapeutic agent is concentrated adjacent to the outer surface of the polymeric coating, and the first therapeutic agent comprises rapamycin and the second therapeutic agent comprises an anti-inflammatory drug are only design choices and within the level of one of ordinary skill in the art.

Therefore, it would have been obvious to combine Sirhan et al with Schwartz and Roorda et al to obtain the invention as specified in the claims.

15. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable Schwartz (US Pub No.: 2003/0235602) in view of Roorda et al (US Pat. No.: 7,175,873) as applied to claim 1 above, and further in view of Hossainy et al (US Pub. No.: 2001/0014717).

In regard to Claims 19 and 20, Schwartz in view of Roorda et al discloses all the limitations of the claim but fails to disclose a primer coating.

However, Hossainy et al explicitly teaches a primer coating disposed on the surface of an implantable device between the implantable device and a reservoir region (Para.[0015]). Hossainy et al further discloses that the primer coating is formed by polyurethane (Para.[0041]).

Schwartz, Roorda et al, and Hossainy et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Schwartz in view of Roorda et al to include a primer coating formed by polyurethane as taught by Hossainy et al.

Applicant should note that it is old and well known in the art that a primer coating is formed between a stent framework and a polymeric coating. The motivation/suggestion for doing so would have been to provide an adhesive tie layer for the stent framework and the drug reservoir layer or the polymeric coating (Hossainy et al, Para.[0015]).

It would have been obvious to one having ordinary skill in the art at the time of the invention was made to form a primer coating with polyurethane, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 125 USPQ 416.*

Therefore, it would have been obvious to combine Hossainy et al with Schwartz and Roorda et al to obtain the invention as specified in the claims.

16. Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable Schwartz (US Pub No.: 2003/0235602) as applied to claim 29 above, and further in view of Hossainy et al (US Pub. No.: 2001/0014717).

In regard to Claims 36 and 37, Schwartz discloses all the limitations of the claim but fails to disclose a primer coating.

However, Hossainy et al explicitly teaches a primer coating disposed on the surface of an implantable device between the implantable device and a reservoir region

(Para.[0015]). Hossainy et al further discloses that the primer coating is formed by polyurethane (Para.[0041]).

Schwartz and Hossainy et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Schwartz to include a primer coating formed by polyurethane as taught by Hossainy et al.

Applicant should note that it is old and well known in the art that a primer coating is formed between a stent framework and a polymeric coating. The motivation/suggestion for doing so would have been to provide an adhesive tie layer for the stent framework and the drug reservoir layer or the polymeric coating (Hossainy et al, Para.[0015]).

It would have been obvious to one having ordinary skill in the art at the time of the invention was made to form a primer coating with polyurethane, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 125 USPQ 416.*

Therefore, it would have been obvious to combine Hossainy et al with Schwartz to obtain the invention as specified in the claims.

Response to Arguments

17. Applicant's arguments with respect to claims 1-7 and 9-20 have been considered but are moot in view of the new ground(s) of rejection.

18. Applicant's arguments filed on 10/09/2008 have been fully considered but they are not persuasive. The allegation on page 9 of the remarks that Schwartz fails to disclose or teach a "the ratio of first fraction of polysulfone to second fraction of styrenic block copolymer is selected so the coating has a predetermined hydrophobicity" is incorrect. Schwartz discloses or teaches that the ratio of first fraction of polysulfone to second fraction of styrenic block copolymer is selected so the coating has a predetermined hydrophobicity (Para.[0012], when the ratio of the first fraction of polysulfone to second fraction of styrenic block copolymer is selected, the hydrophobicity is predetermined).

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JO
/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773